

### REMARKS

Reconsideration and allowance are respectfully requested. The amendments are fully supported by the original disclosure and, thus, no new matter is added by their entry.

Claims 59, 61, 63, 68-69, 71, 73, 78-85 and 91-117 are pending. The nonelected claims 92-97 were withdrawn from consideration by the Examiner. Applicant requests rejoinder of the withdrawn claims directed to methods upon an indication that a product claim is allowable.

Applicant submits herewith a verified translation of the priority Italian application RM98A000478. Acknowledgement that the claim for foreign priority benefit is perfected would be appreciated.

#### *35 U.S.C. 112 – Written Description*

The specification must convey with reasonable clarity to persons skilled in the art that applicant was in possession of the claimed invention as of the filing date sought. See *Vas-Cath v. Mahurkar*, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991). But the Patent Office has the initial burden of presenting evidence or a reason why persons of ordinary skill in the art would not have recognized such a description of the claimed invention in the original disclosure. See *In re Gosteli*, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989).

Claims 59, 61, 63, 68-69, 71, 73, 75-85 and 91 were rejected under Section 112, first paragraph, because it was alleged that they contain "subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention." Applicant traverses because the specification teaches a representative number of species within the claimed genus.

Applicant teaches regulatory elements (e.g., promoter and leader sequence) for a gene encoding soybean protein 7S basic globulin. Another gene encoding soybean protein 7S basic globulin was disclosed by Watanabe et al. (Plant Physiol. 105:1019-1020, 1994). Kagawa et al. (Nucl. Acids Res. 17:8868, 1989) disclosed a cDNA for soybean protein 7S basic globulin. Shu et al. (Accession U59425) disclose another

cDNA for soybean protein 7S basic globulin. As noted on page 6 of the Action, Watanabe et al. indicated that Southern hybridization suggested that at least four copies of genes encoding 7S basic globulin exist in the soybean genome. Taken together, the Applicant's teachings and the knowledge in the art provide more than adequate support for a generic description of the regulatory sequences (e.g., promoters, terminators, enhancers, leader sequences) of the expression cassette. In particular, SEQ ID NO: 21 differs from the corresponding sequence disclosed by Watanabe et al. by about 5%. Applicant also teaches on page 11 of the specification that sequences in the promoter region involved in gene regulation (e.g., CAAT and TATA box sequences, heat shock elements that act as enhancers) have been identified.

One of skill in the art would recognize from the consensus sequences described in the transcriptional regulatory region of the gene for soybean protein 7S basic globulin and the polymorphisms that were known at the time this application was filed that the claimed genus of regulatory sequences is adequately described in Applicant's specification. In contrast, examples in this specification of transcriptional regulatory regions from other soybean genes (e.g., SEQ ID NO: 22 from the  $\beta$  conglycinine genes) teach what does not belong to the claimed genus.

Withdrawal of the written description rejection made under Section 112, first paragraph, is requested because the specification conveys to a person skilled in the art that Applicants were in possession of the claimed invention as of the filing date.

### *35 U.S.C. 112 – Definiteness*

Claim 91 was rejected under Section 112, second paragraph, as being allegedly "indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention." Applicant traverses. The term "suitable" is deleted from claim 91 because this limitation is not required for patentability.

Applicants request withdrawal of the Section 112, second paragraph, rejection because the pending claims are clear and definite.

*35 U.S.C. 102 – Novelty*

A claim is anticipated only if each and every limitation as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of Calif.*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is claimed. See *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

Claims 59, 69, 79-85 and 91 were rejected under Section 102(e) as allegedly anticipated by Legrand et al. (U.S. Patent 6,569,831). Applicant traverses.

The '831 patent was issued on May 27, 2003. The application was filed on March 21, 2000 and the parent Int'l Appln. No. PCT/FR98/00895 was filed on May 4, 1998. Since that international application was filed before November 29, 2000, the '831 patent will have a § 102(e) priority date that is the earlier of the date of compliance with § 371 requirements or the filing date of the U.S. application. The priority date under § 102(e) for the '831 patent is March 21, 2000.

Applicant's earliest claimed priority date is July 17, 1998. A certified copy of the foreign priority application was transmitted by WIPO and attached is an English translation of the Italian priority application. As the pending claims are fully supported by the foreign priority application, the '831 patent is not prior art to this application.

Furthermore, the '831 patent fails to teach promoter and leader sequences from the soybean gene encoding protein 7S basic globulin.

Withdrawal of the Section 102 rejection is requested.

*35 U.S.C. 103 – Nonobviousness*

To establish a case of prima facie obviousness, all of the claim limitations must be taught or suggested by the prior art. See M.P.E.P. § 2143.03. Obviousness can only be established by combining or modifying the prior art teachings to produce the claimed invention if there is some teaching, suggestion, or motivation to do so found in either the references themselves or in the knowledge generally available to a person of ordinary skill in the art. See, e.g., *In re Fine*, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988); *In re Jones*, 21 USPQ2d 1941, 1943-44 (Fed. Cir. 1992).

Claims 59, 69, 79-85 and 91 were rejected under Section 103(a) as allegedly unpatentable over Salmon et al. (Prot. Express. Purif. 13:127-135, 1998) in view of Parmenter et al. (Plant Mol. Biol. 29:1167-1180, 1995) and van der Geest et al. (Plant Mol. boil. 32:579-588, 1996). Applicants traverse.

Salmon et al. do not disclose a plant expression cassette or a recombinant DNA vector that expresses human lactoferrin in seed, or DNA sequences comprising the promoter and the leader sequence of soybean protein 7S basic globulin.

The failure of Salmon et al. to teach or suggest the claimed invention is not remedied by the attempt to modify that disclosure with Parmenter et al. and van der Geest et al. Parmenter et al. disclose the oleosin promoter and leader sequences from Arabidopsis, whereas van der Geest et al. disclose the  $\beta$  phaseolin promoter and leader sequences from Phaseolus. The cited references fail to teach or suggest using the promoter and leader sequences from the soybean gene encoding protein 7S basic globulin.


Withdrawal of the Section 103 rejection is requested because the invention as claimed would not have been obvious to a person of ordinary skill in the art at the time it was made.

Having fully responded to all of the pending objections and rejections contained in this Office Action, Applicant submits that the claims are in condition for allowance and earnestly solicit an early Notice to that effect. The Examiner is invited to contact the undersigned if any further information is required.

Respectfully submitted,

**NIXON & VANDERHYE P.C.**

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